

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

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Serial No.: 10/038,984

Confirmation No.: 9705

Filed: January 4, 2002

For: COMPOSITION AND METHOD FOR IN VIVO AND IN VITRO ATTENUATION OF GENE  
EXPRESSION USING DOUBLE STRANDED RNA

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**Amendments to the Drawings**

The attached sheet of drawings includes changes to Figure 13. This sheet, which includes Figure 12 and 13, replaces the substitute sheet including Figures 12 and 13, filed on April 28, 2003. A marked-up copy of the Figure, labeled "Annotated Sheet Showing Changes," is also included for the Examiner's convenience.

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**COMPOSITION AND METHOD FOR IN VIVO AND IN VITRO ATTENUATION OF GENE EXPRESSION USING DOUBLE STRANDED RNA**

### **Remarks**

The Office Action mailed June 14, 2005 has been received and reviewed.. The pending claims were claims 1-7, 9, 10, 15-25, 27-32, 39, 48, and 61-80, of which claims 61, and 64-67 were withdrawn and claims 8, 11-14, 26, 33-38, 40-47, and 49-60 were canceled. Claims 75 and 76 were allowed, and claim 21 was objected to.

### **Amendments to the Claims**

Claims 1, 6, 20-24, 27, 28, 31, 32, 48, 63, and 72-74 are currently amended. Please cancel claims 9, 10, 25, 61, 64-71, and 77 without prejudice. Support for the amendment to zebrafish cells is found, for example, in Example I on pages 19-35. The currently pending claims are claims 1-7, 15-24, 27-32, 39, 48, 62, 63, 72-76, and 78-80. Reconsideration and withdrawal of the rejections are respectfully requested.

### **Amendments to the Specification and Drawings**

The paragraph beginning at page 8, line 3, has been replaced, as well as the paragraph beginning at page 36, line 10. Figure 13 is also replaced with substitute Figure 13. Applicants have made these amendments to recite murine cells rather than rat cells.

### **The 35 U.S.C. 132 Objection**

The Examiner has maintained the objection to the amendments to the specification and figures in the amendment filed April 28, 2003 that changed the recitation of murine cells to rat cells. Applicants respectfully traverse the objection, but in the interest of furthering prosecution, Applicants have amended the specification and figures to remove recitation of rat cells and return to recitation of mouse cells. The language of the specification at the amended paragraph and Figure 13 is now identical to the language present at the time of filing. Reconsideration and withdrawal of the objection is respectfully requested.

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DOUBLE STRANDED RNA**Page 12 of 14***The 35 U.S.C. §112, First Paragraph, Rejection**

The Examiner has maintained the rejection of claims 1-7, 9, 10, 15-20, 22-25, 27-32, 39, 48, 62, 63 and 68-74, and has rejected new claims 77-80 under 35 U.S.C. §112, first paragraph, for reasons of record, alleging that the specification, "while being enabling for a method of attenuating the expression of target genes in zebrafish cells or embryos, avian neural crest tissue explant culture and in rat [murine NIH/3T3] cell culture, does not reasonably provide enablement for attenuating the expression of any gene in vivo in any vertebrate cell except zebrafish embryos" (Office Action, p. 3). Applicants respectfully traverse the rejection. However, to further prosecution of the application, Applicants have amended independent claims 1, 48, and 63, as well as their dependent claims, to recite attenuation of expression of a target gene in zebrafish cells. Attenuation of expression of a target gene in zebrafish cells is described, for example, in Example I of the present application. As the Examiner has stated that the specification is enabling for a method of attenuating the expression of target genes in zebrafish cells or embryos, Applicants respectfully request that the rejection of claims under 35 U.S.C. §112, first paragraph, for lack of enablement be withdrawn.

The Examiner further rejected Claim 77 for failing to comply with the written description requirement. Applicants have canceled claim 77, rendering the rejection of claim 77 moot.

**Allowable Subject Matter**

Applicant notes with appreciation the indication that claims 75 and 76 are allowable, and that claim 21 would be allowable if rewritten in independent form, including all the limitations of the base claim and any intervening claims. Claim 21 has been amended as requested by the Examiner to recite the subject matter of the base claim (claim 1) and the intervening claim (claim 20).

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COMPOSITION AND METHOD FOR IN VIVO AND IN VITRO ATTENUATION OF GENE EXPRESSION USING DOUBLE STRANDED RNASummary

It is respectfully submitted that the claims 1-7, 15-24, 27-32, 39, 48, 62, 63, 72-76, and 78-80, under examination are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for  
LI et al.

By  
Mueting, Raasch & Gebhardt, P.A.  
P.O. Box 581415  
Minneapolis, MN 55458-1415  
Phone: (612) 305-1220  
Facsimile: (612) 305-1228  
Customer Number 26813

Sept 14, 2005  
Date

By: David C. Provence  
David Provence  
Reg. No. 43,022  
Direct Dial (612) 305-1005

VAS/SJT

CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 14 day of Sept., 2005, at 11:35 A.M. (Central Time).

By: Sandy Truehart  
Name: Sandy Truehart

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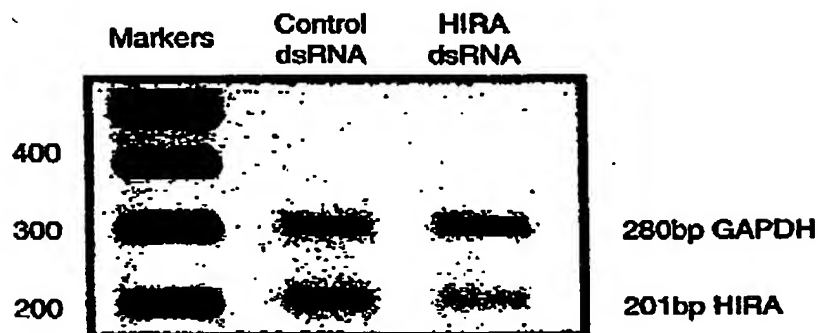
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**ATTACHMENT - REPLACEMENT SHEET(S)****Serial No.: 10/038,984****Docket No.: 275.0003 0102**

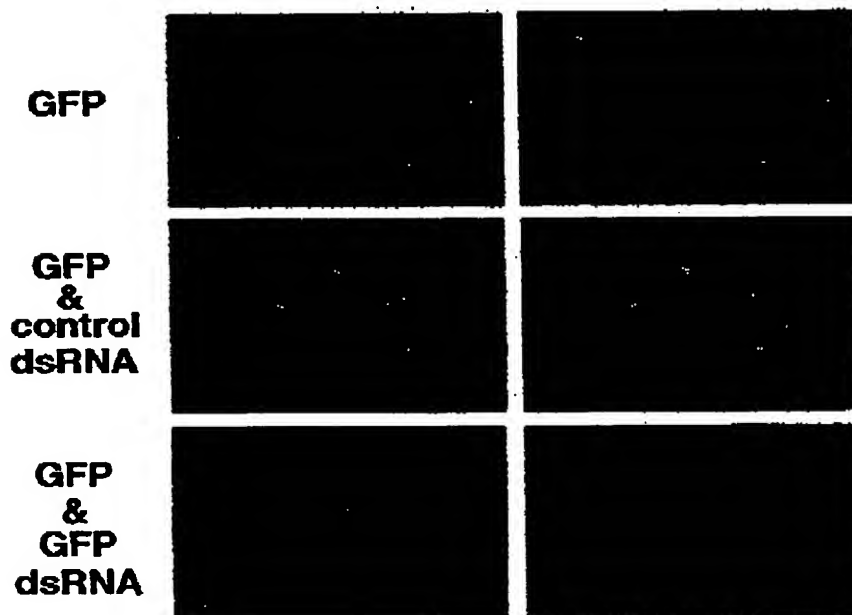
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Pursuant to 37 C.F.R. §1.121(d), attached is an amended Figure 13, labeled "Replacement Sheet," which replaces the Figure 13 in the present application. Also attached is a marked up copy, labeled "Annotated Marked-Up Drawing," of the amended Figure 13 to show the amendments.

## ANNOTATED SHEET SHOWING CHANGES

*Fig. 12*

dsRNA effect on ~~fat~~ <sup>MICE NIH/3T3</sup> Cell Line

*Fig. 13*

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